Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Mylan Laboratories Limited submitted in 2013 an application for [TB286 trade name]* (TB286) to be assessed with the aim of including [TB286 trade name] in the list of prequalified medicinal products for tuberculosis.

[TB286 trade name] was assessed according to the '*Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies*' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

2. Steps taken in the evaluation of the product

November 2013	During the meeting of the assessment team the safety and efficacy data and the quality data were reviewed and further information was requested.
March 2014	The company's response letter was received.
March 2014	During the meeting of the assessment team the additional efficacy data were reviewed and further information was requested.
April 2014	The company's response letter was received.
May 2014	During the meetings of the assessment team the quality data were reviewed and further information was requested.
July 2014	The company's response letters were received.
July 2014	During the meetings of the assessment team the quality data were reviewed and further information was requested. The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
January 2015	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
June 2015	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
September 2015	The company's response letter was received.
September 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
October 2015	The company's response letter was received.
November 2015	During the meetings of the assessment team the quality data were reviewed and further information was requested.
February 2016	The company's response letter was received.
March 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
March 2016	The company's response letter was received.
May 2016	During the meetings of the assessment team the quality data were reviewed and further information was requested.
June 2016	The company's response letter was received.
July 2016	The quality data were reviewed and found to comply with the relevant WHO requirements.
August 2016	Product dossier accepted (quality assurance)
26 October 2016	[TB286 trade name] was included in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

Mylan Laboratories Limited
F-4, F-12, Malegaon M.I.D.C.
Sinnar, Nashik – 422113
Maharashtra state
India

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.

Not inspected for GLP/GCP. No bioequivalence study was required (biowaiver).

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products